Experimentation Description

Introduction

BlueWind Medical Ltd. ("BWM") seeks this experimental license to test its RENOVA iStim™ neuro-stimulation system during clinical trials over a 24-month period. The device is designed for treating patients suffering from symptoms of Over Active Bladder ("OAB"), including urinary urgency incontinence and significant symptoms of urgency-frequency in patients who have failed or could not tolerate more conservative treatments. BWM's RENOVA iStim™ system treats patients while emitting non-ionizing electromagnetic ("EM") energy in the 6.78 MHz industrial, scientific, and medical ("ISM") frequency band near the patient's leg using an External Control Unit ("ECU"). An implant receives the ECU's EM energy and stimulates the patient's internal leg tibial nerve. The ECU and implant also communicate by modulating the EM power transfer to provide a very limited data exchange for managing and controlling the implant for safe and efficient patient treatment.

Expeditiously granting this experimental license will provide patients and healthcare providers access to a potentially low-cost, minimally-invasive, wirelessly powered, and quickly-implantable treatment option for chronic and acute OAB condition1. It will dramatically reduce the massive invasive clinical procedure a patient must undergo prior to treatment. It does not affect the patient's day-to-day routine and does not require any maintenance or physical access while providing care for patients.

RENOVA iStim™ System Components and Functions

RENOVA iStim™ is a peripheral nerve stimulation system intended for home-care use. The system comprises the following components:

- RENOVA iStim™ Implant – a small neurostimulator device that generates mild electrical stimulation, similar to a pacemaker. The implant is placed within the lower leg by a surgeon, using a minimally-invasive surgical technique.

- RENOVA iStim™ ECU – an external wearable device used to control therapy. This device acts like a wireless 'power supply' to the RENOVA iStim™ Implant, enabling control and management of the treatment, including start/stop treatment sessions and adjustment of the stimulation pulses' strength, to maintain a comfortable level of stimulation. The ECU houses a fixed rechargeable battery as its source of power, the electronics and antenna for the EM energy emission that powers and communicates with the implant, electronic circuitry for communication with the Clinician Programmer ("CP") described below, battery management, and device control.

- CP – an off–the-shelf tablet with dedicated software, which is used by a health care provider, to communicate with the ECU via a Federal Communications Commission-certified Bluetooth Low Energy device. The CP is the physician interface for treatment control, status evaluation, parameter programming, and data acquisition.

[1] The Commission has previously granted experimental licenses for similar medical device technologies. *See*, *e.g.*, Grant, Axonics Modulation Technologies, Inc., ELS File No. 0288-EX-CN-2017 (granted Jun. 6, 2017); Grant, EnteroMedics Inc., ELS File No. 0135-EX-PL-2007 (granted Jul. 17, 2007).

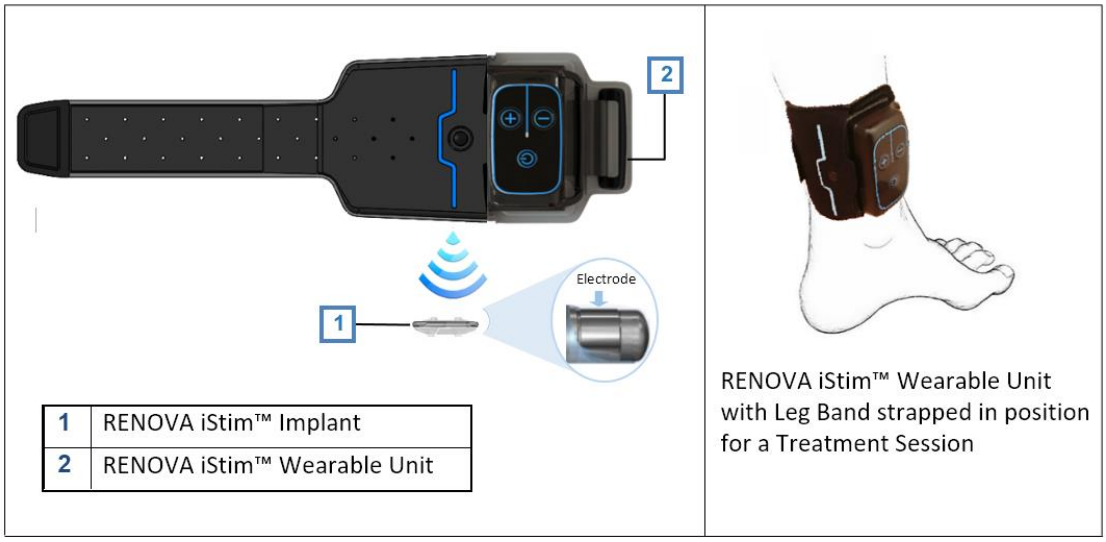

Figure 1 – The RENOVA iStim™ *System's ECU and Implant*

Power is transmitted on the 6.78 MHz ISM frequency, and communication is achieved by modulating the power carrying signal. The risk of harmful interference, even with nationwide licensing, should be extraordinarily low considering both the low power involved (1.44 watts) and the use of a frequency that is centered in an ISM band, which is an unlikely choice for other users' critical communications.

Clinical Trial Description

BWM wishes to evaluate the safety and efficacy of the RENOVA iStim™ System therapy in clinical trials involving approximately 150 patients nationwide. After implantation at the medical facility, patients will be free to go home with the devices. They will use the devices each day of the 24-month follow-up period while going about their normal daily activities. Patients must return to the hospital at designated intervals for follow-up evaluations by the clinicians.